

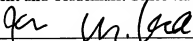
U.S. Patent Application Serial No. 10/723,692
Reply Brief Under 37 C.F.R. §41.41
Docket No. 46521-56177

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of: James B. McCormick	:	Customer No. 021888
	:	
U.S. Patent Application Serial No. 10/723,692	:	Confirmation No. 8923
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Filed: November 26, 2003	:	Examiner: Jarrett, Lore
	:	
For: HISTOLOGICAL SPECIMEN	:	Group Art Unit: 1797
RETAINING DEVICE	:	
	:	Attorney Docket No. 46521-56177

Reply Brief Under 37 C.F.R. §41.41

Submitted herewith is Applicant's Reply Brief in response to the Examiner's Answer of September 17, 2010.

(1) Real Party in Interest

The real party in interest in this Appeal is Leica Biosystems Richmond, Inc. by an assignment recorded on March 26, 2010, at Reel No. 024144, Frame No. 0667.

(2) Related Appeals and Interferences

There are no related appeals or interferences.

(3) Status of Claims

Claims 1-7 are pending in the application. Claims 1-7 have been given a Final Rejection. This is an appeal of the Final Rejection of Claims 1-7. Claims 8-10 were previously cancelled in an amendment dated January 7, 2008.

(4) Status of Amendments

An amendment was filed on June 28, 2010 to rectify a mere typographical error in Claim 1. No new matter was added.

(5) Summary of Claimed Subject Matter

Although Claims 1-7 have been given a Final Rejection, only Claim 1 is an independent claim.

Independent Claim 1

The subject matter of the invention defined by independent Claim 1 is a histological specimen retaining device for processing tissue that is identified by

numeral 10 in FIG. 1. This includes a foldable histological examination liquid permeable sheet 12 having edges (See FIG. 1); a histological examination liquid permeable target 14 disposed on the foldable liquid permeable sheet 12 within the edges (See FIG. 1) of said foldable histological examination liquid sheet 12 and attached with a glue spot (See FIG. 2A), thereby providing extended flap portions 16a-d which flap portions 16a-d are foldable to overlap the histological examination liquid permeable target 14; and a malleable material securing strip 18 attached to the foldable histological examination liquid permeable sheet 12 of a length sufficient to secure said folded flap portions overlapping said histological examination liquid permeable target 14. Applicants' Published Specification, i.e., U.S. Patent Application No. 2005/0112032 in Paragraph [0017], Lines 1-6, Paragraph [0020], Lines 1-13 and Paragraph [0026], Lines 1-10.

(6) Grounds of rejection to be reviewed on Appeal

The grounds of rejection to be reviewed on Appeal is the final rejection of Claims 1, 2 and 6 under 35 U.S.C. § 102(b) for being unpatentable over Pagano (U.S. Patent No. 3,996,006). The grounds of rejection to be reviewed on Appeal also include the final rejection of Claims 3 and 4 under 35 U.S.C. § 103(a) for being unpatentable over Pagano (U.S. Patent No. 3,996,006) in view of Rochette (U.S. Patent No. 3,537,636). Moreover, the grounds of rejection to be reviewed on Appeal include the final rejection of Claim 5 under 35 U.S.C. § 103(a) for being unpatentable over Pagano (U.S. Patent No. 3,996,006) in view of Williamson (U.S. Patent No. 5,817,032). Also, the grounds of rejection to be reviewed on Appeal also include the final rejection of

Claim 7 under 35 U.S.C. § 103(a) for being unpatentable over Pagano (U.S. Patent No. 3,996,006) in view of Lorincz (U.S. Patent No. 5,812,312). Finally, the grounds of rejection to be reviewed on Appeal also include the final rejection of Claims 1, 2 and 6 under 35 U.S.C. § 103(a) for being unpatentable over Larka et al. (U.S. Patent No. 5,932,430) in view of Pagano (U.S. Patent No. 3,996,006).

(7) Response to Examiner's Argument

Claim Rejections – 35 U.S.C. § 102(b)

Claims 1, 2 and 6 were rejected under 35 U.S.C. § 102(b) for being unpatentable over Pagano (U.S. Patent No. 3,996,006).

Independent Claim 1

The cardboard 2 in Pagano is clearly impermeable. The entire concept is to protect the sheet of absorbent paper 26. It is respectfully believed that the foldable cardboard 2 must perform a function in Pagano. If both the cardboard 2 and the absorbent sheet 26 were permeable. There would be no need to open the cardboard flap 2 in Pagano to apply the reagent to the absorbent paper 26. It can be applied directly through the cardboard 2. Pagano recites in Column 2, Lines 24-40: "To use the slide device, the patient separates cover 8 from panel 4 at the spot 52, **opens the cover** and applies with an applicator a thin smear of a specimen from one portion of his stool on paper 26 through opening 22. He then applies from another portion of his stool a thin smear on paper 26 through opening 24. **He then closes the cover locking tab 14 in openings 16 and 18** and returns the slide to his physician. On receiving the

slide, the physician pulls tabs 38 and 40 free of rear panel 6 and opens them outwardly. Through the opening thus made the physician applies a peroxide solution on the guaiac impregnated paper 26 opposite each of the openings 22 and 24 and observes the test results, i.e., in the occult blood test the degree to which the color blue is developed. This provides a good side-by-side comparison of test results from two different portions of the patient's stool." (emphasis added). Therefore, Pagano discloses a stool-sampling device that has the cardboard function to protect the stool sample. This protection would be completely eliminated if the cardboard was permeable.

The glue spots 28 and 34 in FIG. 1 operate to form a boundary on the absorbent paper 26. Therefore, two separate stool samples can be present on the same piece of absorbent paper with this boundary in between. The cardboard blank 2, must by necessity, be impermeable since fluid coming in contact with the cover 8 of the cardboard blank 2 would spread across the entire cover 8 contaminating both samples. The only way the cover works is that it protects the two sections of absorbent paper (separated by a glue boundary) from contamination. A permeable cover 8 would contaminate both specimens and not protect them as required.

Moreover, Applicant defines "permeable sheet" in a manner that clearly differentiates itself from the impermeable cardboard blank 2, where the cover 8 must by necessity be impermeable in order for the invention of Pagano to function. If the cover 8 is permeable, not only would the specimen risk contamination but the lifting of the cover 8 would be a pointless exercise and the reagent could be applied directly to the top of the cover 8.

The Examiner is focusing on the term “could be” contaminated made in the arguments. To be perfectly clear, if permeable cardboard was used as the cover 8 in Pagano, it would by necessity be contaminated. Not only would any contact with liquid or moisture dilute the stool sample, but the liquid would flow across the entire cover 8. This would render the glue spot boundary 28, in FIG. 2, meaningless since fluid could flow across the cover 8 to contact both stool samples 22 and 24.

In addition, it is not a question of whether Pagano is nonanalogous or teaches away, but that anyone reading this reference would clearly know that the cardboard in Pagano must inherently be impermeable in order for the device to function based on reading Pagano. The flaps provide some purpose and if the cardboard cover 8 was permeable, the stool samples would be contaminated and liquid would flow to both openings 22 and 24 in the absorbent paper 26 via the cover 8 thereby rendering the glue barrier 28 meaningless. It is respectfully believed that Pagano must be interpreted in a manner so that the invention functions. A permeable cardboard cover would not function. Also, anyone remotely familiar with a stool sample device would be well aware that the device is surrounded by an impermeable piece of cardboard for protection of the stool sample. A doctor cannot be concerned that moisture is going to contaminate the stool sample, which would be the case if the cover 8 was permeable.

The argument is not whether Pagano is analogous or in a different field but that “the identical invention must be shown in as complete detail as is contained in the...claim” under 35 U.S.C. §102 *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). In this case, anyone using a stool

sample device would find that the cardboard cover must inherently be **impermeable** or the device would be easily contaminated and would not function.

Pagano's device is only open to apply reagent to a stool sample and protects the stool sample when closed. It is not for overlapping a tissue target for processing tissue with fluids where the liquid permeable sheet is folded over the target.

The argument made by the Examiner on Page 14, Lines 1-3 that "Applicant's sheet is also impermeable since it also must be open to receive a sample or the like" seems to indicate that the Examiner has now abandoned his argument that Pagano is permeable cardboard and is now trying to allege that Applicant's device is now impermeable. This contradicts the clear language of Claim 1 and the Applicant's patent application. Moreover, contrary to the Examiner's assertion, the structure of Applicant's invention is not remotely similar to Pagano. Applicant's claimed device is a foldable liquid permeable sheet having extended flap portions which flap portions are foldable to overlap the liquid permeable target, where the liquid is histological examination liquid. In marked contrast, Pagano discloses in Column 1, Lines 64-68: "Front panel 4 has a pair of adjacent openings 22 and 24. A sheet of absorbent paper 26, for example, filter paper overlies (as viewed in FIG. 1) openings 22 and 24. Sheet 26 is **impregnated with a reagent such as guaiac.**" (emphasis added). If the flap was liquid permeable, the absorbent paper impregnated with a reagent could be ruined by liquid passing through the flap into the absorbent paper. The reason for the flap in Pagano is so that the absorbent paper is only exposed to fecal matter when acquiring a stool specimen and then open to receive peroxide solution during testing to develop the reagent. Liquid passing onto the absorbent paper would literally destroy the absorbent

paper for its desired purpose by diluting and removing both the stool specimen and the reagent. Therefore, Pagano and the Applicant's claimed invention are very different devices. It is respectfully believed that it is not reasonable to state that Pagano is "similar" and therefore must be permeable.

On Page 14, Lines 11-19 of the Examiner's Answer, the Examiner believes that the Applicant's use of the term "if" to describe how having permeable cover 8 in Pagano would destroy Pagano for its stated purpose negates the argument. The reality is that Pagano, as described in Pagano, cannot function with a permeable cover 8. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). In this case, when a claim limitation cannot be present in Pagano, then Pagano cannot anticipate.

The focus by the Examiner on Page 15, Lines 3-4 of the Examiner's Answer on nonanalogous art or teaching away is completely misplaced. The reality is that a stool sample device would not function if the protective outer cover is made of permeable material.

On Page 16, Line 5 of the Examiner's Answer, Pagano absolutely does not disclose a sheet that is inherently permeable, but rather a cardboard cover that is inherently impermeable. Also, contrary to Page 17, Lines 15-16 of the Examiner's Answer, Pagano is not inherently permeable.

On Page 18, Lines 14-20 of the Examiner's Answer, it is respectfully believed that the glue spots are to create an impermeable boundary in the absorbent material.

Having permeable cardboard as the cover would allow liquid to flow on top to both stool specimen compartments. This would destroy the function of the glue spot boundary by allowing liquid to flow between the two compartments through the cover. Therefore, it is respectfully believed that the Examiner's interpretation contradicts a plain reading of Pagano and the inherent logical premises that result.

On Page 19, Lines 12-16 of the Examiner's Answer, it is respectfully believed that a hard cardboard tab is not the same as a piece of "malleable material." Under 35 U.S.C. §102, "the identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

On Page 20, Lines 13-20 of the Examiner's Answer, it is respectfully believed that the glue creates impermeable boundaries in the absorbent material. It is not used for attaching a tissue target to the inside of a permeable sheet that is folded around it.

On Page 21, Lines 10-21 of the Examiner's Answer, it is respectfully believed that a foldable liquid permeable sheet having extended flap portions which flap portions are foldable to overlap the liquid permeable target, where the liquid is histological examination liquid is very different than a stool sample device where the patient **opens the cover** and applies with an applicator a thin smear of a specimen from one portion of his stool on paper 26 through opening 22. He then applies from another portion of his stool a thin smear on paper 26 through opening 24. **He then closes the cover locking tab 14 in openings 16 and 18** and returns the slide to his physician. On receiving the slide, the physician pulls tabs 38 and 40 free of rear panel 6 and opens them outwardly. **Through the opening thus made the physician applies a peroxide**

solution on the guaiac impregnated paper 26 opposite each of the openings 22 and 24 and observes the test. (Pagano, Column 2, Lines 24-40). To eliminate all of the terms in the claim like "histological" and "processing tissue" so that the pretense of a radically different device that is used for a very different purpose somehow anticipates the applicant's invention does not comply with 35 U.S.C. §102, where "the identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

On Page 22, Lines 10-14 of the Examiner's Answer, the Examiner asserts that numeral 52 is a tab. This directly contradicts Column 2, Lines 22-23 of Pagano that directly recites: "Cover 8 is now hinged about crease 12 and secured to panel 4 by a spot of glue 52." (emphasis added).

On Page 23, Lines 7-9 of the Examiner's Answer, the Examiner asserts that glue 28, 32 and 34 are to adhere the permeable target to panels 4 and 6 when the reality it is to provide impermeable boundaries in the absorbent material 26 so that two stool specimens can be placed side-by-side and tested. The function of this glue boundary would be negated if the outer cover 8 is permeable.

Therefore, it is respectfully believed that the rejection of Claim 1 under 35 U.S.C. § 102(b) as being unpatentable over Pagano should be reversed.

Dependent Claim 2

Claim 2 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 102(b) rejection over Pagano in the same manner as Claim 1

as described above. "If an independent claim is not anticipated, then any claim depending therefrom is also not anticipated." *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

In addition, Claim 2 recites: "wherein the malleable material securing strip is attached at an edge of the histological examination liquid permeable sheet **to allow for closure and clamping of the folded flap portions as well as positive release of the folded flap portions.**" (emphasis added). In marked contrast, Column 2, Lines 22-23 of Pagano directly recites: "Cover 8 is now hinged about crease 12 and secured to panel 4 by a **spot of glue 52.**" (emphasis added). This directly contradicts the Examiner's argument on Page 33, Lines 17-21 of the Examiner's Answer.

Moreover, a hard cardboard tab disclosed in Pagano should not be construed as a malleable strip. Under 35 U.S.C. §102, "the identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

Therefore, it is respectfully believed that the rejection of Claim 2 under 35 U.S.C. § 102(b) as being unpatentable over Pagano should be reversed.

Dependent Claim 6

Claim 6 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 102(b) rejection over Pagano in the same manner as Claim 1 as described above. "If an independent claim is not anticipated, then any claim depending therefrom is also not anticipated." *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

In addition, Claim 6 recites: "wherein the histological examination liquid permeable target is a liquid permeable **paper sheet** having a glue spot located thereon for attaching the histological examination liquid permeable target to the foldable histological examination liquid permeable sheet." (emphasis added). Moreover, Claim 6 requires that the histological examination liquid permeable target be attached to the foldable histological examination liquid permeable sheet with a spot of glue. In marked contrast, the glue in Pagano is to "...form the completed slide 50 shown in FIG. 2, blank 2 is folded along crease line 10 to bring panels 4 and 6 together and hold them together principally by the glue at 35. Cover 8 is now hinged about crease 12 and secured to panel 4 by a spot of glue 52." (Pagano, Column 2, Lines 19-23). It is to fold the panels of the blank together and not secure a histological examination liquid permeable target to a foldable histological examination liquid permeable sheet. Under 35 U.S.C. §102, "the identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

Therefore, it is respectfully believed that the rejection of Claim 6 under 35 U.S.C. § 102(b) as being unpatentable over Pagano should be reversed.

Claim Rejections – 35 U.S.C. § 103(a)

Claims 3 and 4 were rejected under 35 U.S.C. § 103(a) for being unpatentable over Pagano (U.S. Patent No. 3,996,006) in view of Rochette (U.S. Patent No. 3,537,636).

Dependent Claim 3

Claim 3 depends from dependent Claim 2 and independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 103(a) rejection over Pagano in the same manner as Claim 1 as described above. "If an independent claim is not obvious, then any claim depending therefrom is also not obvious." *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

On Page 23 of the Examiner's Answer, the Examiner again asserts that numeral 52 is a tab. This directly contradicts Column 2, Lines 22-23 of Pagano that directly recites: "Cover 8 is now hinged about crease 12 and secured to panel 4 by a **spot of glue 52.**" (emphasis added).

Claim 3 requires that the malleable securing strip is a **metal wire**. This does not mean the malleable securing strip includes or comprises a metal wire **but the malleable securing strip is a metal wire**.

Pagano does not disclose a malleable securing strip but rather a tab. For example, Applicant's Published Patent Application, i.e., U.S. Published Patent Application No. 20050112032, recites: "Again referring to FIG. 1, histological retaining device comprises a malleable securing strip 18. When extended flap portions 16a-d are folded to overlap target 14 (described in more detail below), **malleable securing strip 18 is designed to hold, crimp, or clamp the folded extended flap portions 16a-d to target 14; thereby, securing the extended flap portions 16a-d in the folded condition.** Additionally, malleable securing strip 18 provides positive release upon the opening of folded flap portions 16a-d after processing of the sample." (emphasis added)

(Paragraph [0026], Lines 1-10). Also: “Malleable securing strip 18 can be **any material that is formable or malleable**, but it is **preferred that strip 18 is either a metal wire or a strip of heavy metal foil**. The **wire or foil needs to have appropriate dimensions to allow for a one time use-easy closure and clamping**, as well as, **positive release of extended flap portions 16a-d** (described in more detail below).” (emphasis added) (Paragraph [0028], Lines 1-7). In marked contrast in Pagano, the area marked by numeral 52 is described as “Cover 8 is now hinged about crease 12 and secured to panel 4 by a **spot of glue 52**.” (Pagano, Column 2, Lines 22-23) (emphasis added). The area where numeral 52 is located is identified by the Examiner as corresponding to the malleable securing strip. It is respectfully believed that a tab would not be formed from a bendable piece of wire.

Using a piece of wire instead of a cardboard tab does not provide any added function and makes it more difficult to place in the slit if the metal wire is bent in any manner. A person of ordinary skill in the art would not utilize a secondary reference if the additional feature from the secondary reference makes the function of the device less operable than prior to the modification. Having a piece of metal wire attached to the cover 8 in Pagano would require that the wire or metal remain perfectly straight in order to place the tab in the slit. It would be less flexible than using the cardboard slot by itself. The Examiner states that “it would appear that persons skilled in the art would recognize that having a bendable metal wire or metal foil in place of Pagano's tab would not destroy the function and purpose of Pagano's device.” To the contrary, it is respectfully believed that having a bent piece of metal wire instead of a hard cardboard tab would be more difficult to place in the slot since metal wire easily bends. The use

of metal wire for the tab would make the job of inserting the tab into the slot much more difficult since the metal wire must be kept perfectly straight. When the metal wire contacts the cardboard near the slot, it will bend while a cardboard slot will remain rigid for easy insertion into the slot. A person of ordinary skill in the art would not substitute a metal wire slot for a cardboard slot since it makes the task of inserting the tab into the slot extremely difficult and for the device in Pagano, there is no motivation to do so. "If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). Moreover, "all words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

"To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, **with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference**; (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it **did separately**." (emphasis added). Federal Register / Volume 72, No. 195 / Wednesday, October 10, 2007 / Notices, Page 57529, "*Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court*

Decision in KSR International Co. v. Teleflex Inc." It is respectfully believed that it is very clear that this rejection completely fails the new KSR Guidelines promulgated by the United States Patent Office since a metal wire would make a horrible tab that is vastly inferior to the current cardboard tab disclosed in Pagano.

Therefore, it is respectfully believed that the rejection of Claim 3 under 35 U.S.C. § 103(a) as being unpatentable over Pagano in view of Rochette should be reversed.

Dependent Claim 4

Claim 4 depends from dependent Claim 2 and independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 103(a) rejection over Pagano in the same manner as Claim 1 as described above. "If an independent claim is not obvious, then any claim depending therefrom is also not obvious." *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

Claim 4 requires that the malleable securing strip is a **metal foil**. This does not mean the malleable securing strip includes or comprises a metal foil **but the malleable securing strip is a metal foil**.

Pagano does not disclose a malleable securing strip but rather a tab. For example, Applicant's Published Patent Application, i.e., U.S. Published Patent Application No. 20050112032, recites: "Again referring to FIG. 1, histological retaining device comprises a malleable securing strip 18. When extended flap portions 16a-d are folded to overlap target 14 (described in more detail below), **malleable securing strip 18 is designed to hold, crimp, or clamp the folded extended flap portions 16a-d to**

target 14; thereby, securing the extended flap portions 16a-d in the folded condition. Additionally, malleable securing strip 18 provides positive release upon the opening of folded flap portions 16a-d after processing of the sample." (emphasis added) (Paragraph [0026], Lines 1-10). Also: "Malleable securing strip 18 can be **any material that is formable or malleable**, but it is **preferred that strip 18 is either a metal wire or a strip of heavy metal foil**. The **wire or foil needs to have appropriate dimensions to allow for a one time use-easy closure and clamping**, as well as, **positive release of extended flap portions 16a-d** (described in more detail below)." (emphasis added) (Paragraph [0028], Lines 1-7). In marked contrast in Pagano, the area marked by numeral 52 is described as "Cover 8 is now hinged about crease 12 and secured to panel 4 by a **spot of glue 52**." (Pagano, Column 2, Lines 22-23) (emphasis added). The area where numeral 52 is located is identified by the Examiner as corresponding to the malleable securing strip. It is respectfully believed that a tab would not be formed from a bendable piece of metal foil.

Using a piece of metal foil instead of a cardboard tab does not provide any added function and makes it more difficult to place in the slit if the metal wire is bent in any manner. A person of ordinary skill in the art would not utilize a secondary reference if the additional feature from the secondary reference makes the function of the device less operable than prior to the modification. Having a piece of metal foil attached to the cover 8 in Pagano would require that the metal foil remain perfectly straight in order to place the tab in the slit. It would be less flexible than using the cardboard slot by itself. The Examiner states that "it would appear that persons skilled in the art would recognize that having a bendable metal wire or metal foil in place of Pagano's tab

would not destroy the function and purpose of Pagano's device." To the contrary, it is respectfully believed that having a bent piece of foil instead of a hard cardboard tab would be more difficult to place in the slot since the metal foil easily bends. The use of metal foil tab for the cardboard tab would make the job of inserting the tab into the slot much more difficult since the metal foil must be kept perfectly straight. When the metal foil contacts the cardboard near the slot, it will bend while a cardboard slot will remain rigid for easy insertion into the slot. A person of ordinary skill in the art would not a substitute metal foil tab for a cardboard tab since it makes the task of inserting the tab into the slot extremely difficult and for the device in Pagano, there is no motivation to do so. "If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). Moreover, "all words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

"To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, **with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference**; (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it

did separately." (emphasis added). Federal Register / Volume 72, No. 195 / Wednesday, October 10, 2007 / Notices, Page 57529, "*Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*" It is respectfully believed that it is very clear that this rejection completely fails the new KSR Guidelines promulgated by the United States Patent Office since a metal foil would make a horrible tab that is vastly inferior to the current cardboard tab disclosed in Pagano.

Therefore, it is respectfully believed that the rejection of Claim 4 under 35 U.S.C. § 103(a) as being unpatentable over Pagano in view of Rochette should be reversed.

Dependent Claim 5

Claim 5 was rejected under 35 U.S.C. § 103(a) for being unpatentable over Pagano (U.S. Patent No. 3,996,006) in view of Williamson (U.S. Patent No. 5,817,032).

Claim 5 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 103(a) rejection over Pagano in the same manner as Claim 1 as described above. "If an independent claim is not obvious, then any claim depending therefrom is also not obvious." *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

The Examiner on Page 25, Lines 1-3 of the Examiner's Answer that having a binder on the stool sample would improve Pagano's invention since it will "...insure

that the loose and/or smaller pieces of the sample would remain on Pagano's permeable target (26) during transport to the physician's office."

This response completely ignores the fact that the target in Pagano is a stool sample. The addition of a reagent to the stool sample makes sense because there is a chemical reaction with the stool sample to determine the presence of occult blood. Therefore, the complete access to the stool sample is required so that a chemical reaction can take place. A binder would operate to prevent a chemical reaction from occurring. The Examiner has stated on Page 4, Lines 11-21 of the September 3, 2009 Office Action that: "Williamson discloses in his abstract placing a **tissue biopsy sample on a tissue trapping** and supporting material that can withstand tissue preparation procedures and which can be cut with a microtome. Williamson further discloses spraying a **thin layer of agar or other gel over the tissue** and filter (i.e., col. 16, lines 43-59). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Pagano's liquid permeable target by adding a **binder, such as agar, to the tissue sample** because adding agar to tissue samples is well known as "cell block preparation," which is a technique that allows the user to easily prepare the sample for analysis (i.e., Williamson, Column 1, Lines 32-37)." (emphasis added). Therefore, adding a binder and using a tissue trapping material would operate to destroy the invention disclosed in Pagano and prevent an even and consistent chemical reaction between the stool sample and the reagent from taking place. "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of

the references are not sufficient to render the claims prima facie obvious." *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959).

"To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference; (2) **a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately.**" (emphasis added). Federal Register / Volume 72, No. 195 / Wednesday, October 10, 2007 / Notices, Page 57529, "*Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*" It is respectfully believed that it is very clear that this rejection completely fails the new KSR Guidelines promulgated by the United States Patent Office since adding a binder or gel would most likely operate to prevent or inhibit a reaction between a stool sample and reagent from taking place. It would not be the same function as performed in Claim 5 since no one with ordinary skill in the art would add material that would prevent or inhibit the reaction between the stool sample and the reagent from taking place since that is the purpose and function of Pagano.

Therefore, it is respectfully believed that the rejection of Claim 5 under 35 U.S.C. § 103(a) as being unpatentable over Pagano in view of Williamson should be reversed.

Dependent Claim 7

Claim 7 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 103(a) rejection over Pagano in the same manner as Claim 1 as described above. "If an independent claim is not obvious, then any claim depending therefrom is also not obvious." *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

Claim 7 recites: "...an X and Y coordinate marking lines centered on the histological examination liquid permeable target." Lorincz discloses a: "...reference standards, such as a sizing grid 19 or the like, can also be incorporated as by etching or photographic reproduction onto the surface of the slide or film to allow sizing and quantitation of cells, microorganisms or the like." (Lorincz, Column 4, Lines 44-48). This grid 19 is not a "centered X and Y axis." There is no semblance of **centered X** and Y axis disclosed in Pagano. It is respectfully believed to be axiomatic that a feature not disclosed in two cited references cannot come into being by their combination.

Moreover, this grid 19 in Lorincz appears on a liquid impermeable microscope slide 11 or film 16. There is no reason to use a grid on a liquid **impermeable** surface and transfer that to a histological examination liquid **permeable** target enclosed by the foldable histological examination liquid **permeable** sheet. The grid in Lorincz is required for viewing under a microscope and cannot be enclosed by a foldable histological examination liquid **permeable** sheet. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). "In determining the

propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 U.S.P.Q. 560, 562 [C.C.P.A. 1972].

Moreover, the mere grid in Lorincz is centered on the microscope slide and not the histological examination liquid permeable target. "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 [C.C.P.A. 1959]. In addition, there is no teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference to arrive at the claimed invention. *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385 [U.S. 2007]. In determining obviousness, the proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art after consideration of all the facts. "To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art **being the lack of actual combination of the elements in a single prior art reference**; (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, **each element merely would have performed the**

same function as it did separately." (emphasis added) (Federal Register / Volume 72, No. 195 / Wednesday, October 10, 2007 / Notices, Page 57529, "*Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*"). It is respectfully believed that it is very clear that this rejection completely fails the new KSR Guidelines promulgated by the United States Patent Office since the grid in Lorincz is centered on the microscope slide and not the histological examination liquid permeable target.

Therefore, it is respectfully believed that the rejection of Claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Pagano in view of Lorincz should be reversed.

Independent Claim 1

Claims 1, 2 and 6 were rejected under 35 U.S.C. § 103(a) for being unpatentable over Larka et al. (U.S. Patent No. 5,932,430) in view of Pagano (U.S. Patent No. 3,996,006).

The cardboard 2 in Pagano is clearly impermeable. The entire concept is to protect the sheet of absorbent paper 26. It is respectfully believed that the foldable cardboard 2 must perform a function in Pagano. If both the cardboard 2 and the absorbent sheet 26 were permeable, there would be no need to open the cardboard flap 2 in Pagano to apply the reagent to the absorbent paper 26. It can be applied directly through the cardboard 2. Pagano recites in Column 2, Lines 24-40: "To use the slide device, the patient separates cover 8 from panel 4 at the spot 52, **opens the cover** and applies with an applicator a thin smear of a specimen from one portion of his stool on

paper 26 through opening 22. He then applies from another portion of his stool a thin smear on paper 26 through opening 24. **He then closes the cover locking tab 14 in openings 16 and 18** and returns the slide to his physician. On receiving the slide, the physician pulls tabs 38 and 40 free of rear panel 6 and opens them outwardly.

Through the opening thus made the physician applies a peroxide solution on the guaiac impregnated paper 26 opposite each of the openings 22 and 24 and observes the test results, i.e., in the occult blood test the degree to which the color blue is developed. This provides a good side-by-side comparison of test results from two different portions of the patient's stool." (emphasis added). Therefore, Pagano discloses a stool-sampling device that has the cardboard function to protect the stool sample. This protection would be completely eliminated if the cardboard was permeable.

The glue spots 28 and 34 in FIG. 1 operate to form a boundary on the absorbent paper 26. Therefore, two separate stool samples can be present on the same piece of absorbent paper with this boundary in between. The cardboard blank 2, must by necessity, be impermeable since fluid coming in contact with the cover 8 of the cardboard blank 2 would spread across the entire cover 8 contaminating both samples. The only way the cover works is that it protects the two sections of absorbent paper (separated by a glue boundary) from contamination. A permeable cover 8 would contaminate both specimens and not protect them as required.

Moreover, Applicant defines "permeable sheet" in a manner that clearly differentiates itself from the impermeable cardboard blank 2, where the cover 8 must by necessity be impermeable in order for the invention of Pagano to function. If the cover 8 is permeable, not only would the specimen risk contamination but the lifting of

the cover 8 would be a pointless exercise and the reagent could be applied directly to the top of the cover 8.

Therefore, the absorbent paper 26 found in Pagano could be contaminated if the closure flap was permeable and it was irrelevant as to whether or not the closure flap was open. Therefore, not only does Pagano not disclose this feature, but it would destroy the Applicant's Invention, as claimed, for its stated purpose of providing a foldable liquid permeable sheet having extended flap portions which flap portions are foldable to overlap the liquid permeable target, where the liquid is histological examination liquid.

Moreover, Larka et al. recites: "At the lab, the technician accesses the filter paper 20 through the flap 22 and removes the portions 24 of the paper bounded by the score lines 26 and immerses them in diluent solution such as BSA/PBS to prepare a sample solution which can be used in the assay as previously illustrated in Example 4." (Larka et al., Column 8, Lines 10-15). This paper card 10 clearly appears to be impermeable to fluids and not permeable since there would be no need to open the flap if the paper card 10 was permeable. It is respectfully believed that the combination of two impermeable stool sampling devices, i.e., Pagano and Larka et al., does not create a "histological examination liquid permeable sheet" by their combination. It is respectfully believed that when cardboard is disclosed in a cited reference, there must be analysis by someone of ordinary skill in the art to determine the qualities. If the cardboard must be impermeable in order for the disclosed device to function, then to state that the mere fact that cardboard is disclosed would by necessity make it permeable is without any logical support. In this case, both Pagano and Larka et al.

require liquid impermeability in the cardboard. It is respectfully believed that the specific cardboard in both Pagano and Larka et al. should not be ignored in view of some general premise about cardboard that is not applicable to the cited references.

Contrary to the Examiner's arguments on Page 30, Lines 9-13 of the Examiner's Answer, it is respectfully believed that a permeable sheet is a clearly defined term that allows the passage of histological fluid rather than a piece of cardboard that is used to protect against fluid contamination.

The Examiner also argues on Page 31, Lines 10-11 that Larka discloses: "...a permeable paper card comprising a filter paper affixed to the card with glue." To the contrary, if the card is permeable then there would be no need to open the flap 22 and fluid would flow between the filter paper and the card since the card would now be permeable. The Examiner's interpretation is directly contrary to how this device would function for someone of ordinary skill in the art and would render this device unsatisfactory by allowing fluid contamination between the card and the filter paper. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). "In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 U.S.P.Q. 560, 562 [C.C.P.A. 1972].

Therefore, the combination of Larka et al. and Pagano clearly teaches away from the Applicant's Invention, as claimed, in addition to destroying the Applicant's Invention for its intended purpose. The Supreme Court held in *U.S. v. Adams*, 383 U.S. 39, 148 U.S.P.Q. 479 (1966), that one important indicium of nonobviousness is "teaching away" from the claimed invention by the prior art or by experts in the art at (and/or after) the time the invention was made. This is specifically mandated by the Manual of Patent Examining Procedure (M.P.E.P.) § 2141.02, which recites: "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990).

Consequently, permeability of both the histological examination liquid permeable target and the foldable histological examination liquid permeable sheet is crucial to Applicant's Invention, as claimed. Therefore, "if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious." *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959). Moreover, there is no teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. *KSR*

International Co. v. Teleflex Inc., 82 U.S.P.Q.2d 1385 (U.S. 2007). In determining obviousness, the proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art after consideration of all the facts. "To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art **being the lack of actual combination of the elements in a single prior art reference;** (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, **each element merely would have performed the same function as it did separately.**" (emphasis added) (Federal Register / Volume 72, No. 195 / Wednesday, October 10, 2007 / Notices, Page 57529, "*Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*"). It is respectfully believed that it is very clear that this rejection completely fails the new KSR Guidelines promulgated by the United States Patent Office.

Therefore, it is respectfully believed that the rejection of Claim 1 under 35 U.S.C. § 103(a) for being unpatentable over Larka et al. in view of Pagano should be reversed.

Dependent Claim 2

Claim 2 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 103(a) rejection over Larka et al. in view of Pagano in the

same manner as Claim 1 as described above. "If an independent claim is not obvious, then any claim depending therefrom is also not obvious." *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

In addition, Claim 2 recites: "wherein the malleable material securing strip is attached at an edge of the histological examination liquid permeable sheet **to allow for closure and clamping of the folded flap portions as well as positive release of the folded flap portions.**" (emphasis added). In marked contrast in Pagano, the area identified by numeral 52 as being the malleable material securing strip is either a piece of hard glue that is not located at the edge or just a portion of the blank 2. Pagano does not disclose a malleable securing strip but rather a tab. There does not appear to be any clamping but merely the insertion of a stiff cardboard tab within a slot. If the tab bends or is malleable, it makes it much more difficult to engage the slot.

Moreover, the Examiner on Page 7, Lines 7-10 of the Final Rejection, dated March 1, 2010 states that Larka et al. does not disclose a malleable securing strip. It is respectfully believed that a feature that is not disclosed in either of two cited references cannot come into being by their combination. A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is **not sufficient** to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993). "[R]ejections on obviousness cannot be **sustained by mere conclusory statements**; instead, there must be some articulated

reasoning with some rational underpinning to support the legal conclusion of obviousness." (emphasis added) *In re Kahn*, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006). Manual for Examining Procedure (M.P.E.P. §2143.01 IV).

Therefore, it is respectfully believed that the rejection of Claim 2 under 35 U.S.C. § 102(b) as being unpatentable over Larka et al. in view of Pagano should be reversed.

Dependent Claim 6

Claim 6 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 103(a) rejection over Larka et al. in view of Pagano in the same manner as Claim 1 as described above. "If an independent claim is not obvious, then any claim depending therefrom is also not obvious." *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

In addition, Claim 6 recites: "wherein the histological examination liquid permeable target is a liquid permeable **paper sheet** having a glue spot located thereon for attaching the histological examination liquid permeable target to the foldable histological examination liquid permeable sheet." (emphasis added). Moreover, Claim 6 requires that the histological examination liquid permeable target be attached to the foldable histological examination liquid permeable sheet with a spot of glue. In marked contrast, the glue in Pagano is to "...form the completed slide 50 shown in FIG. 2, blank 2 is folded along crease line 10 to bring panels 4 and 6 together and hold them together principally by the glue at 35. Cover 8 is now hinged about crease 12 and secured to panel 4 by a spot of glue 52." (Pagano, Column 2, Lines 19-23). It is to fold

the panels of the blank together and not secure a histological examination liquid permeable target to a foldable histological examination liquid permeable sheet.

Moreover, Larka et al. recites: "At the lab, the technician accesses the filter paper 20 through the flap 22 and removes the portions 24 of the paper bounded by the score lines 26 and immerses them in diluent solution such as BSA/PBS to prepare a sample solution which can be used in the assay as previously illustrated in Example 4." (Larka et al., Column 8, Lines 10-15). This paper card 10 clearly appears to be impermeable to fluids and not permeable since there would be no need to open the flap if the paper card 10 was permeable. It is respectfully believed that the combination of two impermeable stool sampling devices, i.e., Pagano and Larka et al., does not create a "histological examination liquid permeable sheet" by their combination.

Moreover, "if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). "In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 U.S.P.Q. 560, 562 (C.C.P.A. 1972).

Therefore, the combination of Larka et al. and Pagano clearly teaches away from the Applicant's Invention, as claimed, in addition to destroying the Applicant's Invention for its intended purpose. The Supreme Court held in *U.S. v. Adams*, 383

U.S. 39, 148 U.S.P.Q. 479 (1966), that one important indicium of nonobviousness is "teaching away" from the claimed invention by the prior art or by experts in the art at (and/or after) the time the invention was made. This is specifically mandated by the Manual of Patent Examining Procedure (M.P.E.P.) § 2141.02, which recites: "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Moreover, "...if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990).

Consequently, permeability of both the histological examination liquid permeable target and the foldable histological examination liquid permeable sheet is crucial to Applicant's Invention, as claimed. Therefore, "if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious." *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959). Moreover, there is no teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. *KSR*

International Co. v. Teleflex Inc., 82 U.S.P.Q.2d 1385 (U.S. 2007). In determining obviousness, the proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art after consideration of all the facts. "To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art **being the lack of actual combination of the elements in a single prior art reference;** (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, **each element merely would have performed the same function as it did separately.**" (emphasis added) (Federal Register / Volume 72, No. 195 / Wednesday, October 10, 2007 / Notices, Page 57529, "*Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*"). It is respectfully believed that it is very clear that this rejection completely fails the new KSR Guidelines promulgated by the United States Patent Office.

Moreover, the glue spot 52 disclosed in Pagano is not for attaching a histological examination liquid permeable target to the foldable histological examination permeable sheet. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (C.C.P.A. 1970).

Therefore, it is respectfully believed that the rejection of Claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Larka in view of Pagano should be reversed.

For all the reasons set forth above, it is respectfully submitted that the rejections of Claims 1-7 should be reversed and the Claims allowed.

(8) Claims Appendix

1. A histological specimen retaining device for processing tissue, said device comprising: a foldable histological examination liquid permeable sheet having edges; a histological examination liquid permeable target disposed on the foldable liquid permeable sheet within the edges of said foldable histological examination liquid permeable sheet and attached with a glue spot, thereby providing extended flap portions which flap portions are foldable to overlap the histological examination liquid permeable target; and a malleable material securing strip attached to the foldable histological examination liquid permeable sheet of a length sufficient to secure said folded flap portions overlapping said histological examination liquid permeable target.

2. The histological specimen retaining device of claim 1 further comprising wherein the malleable material securing strip is attached at an edge of the histological examination liquid permeable sheet to allow for closure and clamping of the folded flap portions as well as positive release of the folded flap portions.

3. The histological specimen retaining device of claim 2, wherein the malleable material securing strip is a metal wire.

4. The histological specimen retaining device of claim 2, wherein the malleable material securing strip is metal foil.

5. The histological specimen retaining device of claim 1, further comprising wherein the histological examination liquid permeable target is coated with a release agent.

6. The histological specimen retaining device of claim 1, wherein the histological examination liquid permeable target is a liquid permeable paper sheet having a glue spot located thereon for attaching the histological examination liquid permeable target to the foldable histological examination liquid permeable sheet.

7. The histological specimen retaining device of claim 1, further comprising an X and Y coordinate marking lines centered on the histological examination liquid permeable target.

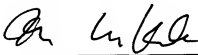
It is respectfully submitted that, for the reasons set forth above, the rejections of Claims 1-7 were made in error and should be reversed and the Claims 1-7 allowed. Moreover, the use of a stool sample in a prior art rejection was already decided in favor of the Applicant with regard to Claims 8-10 found in U.S. Patent Application No. 11/742,647 of the original patent application before the Board of Patent Appeals and Interferences and the same Examiner. A similar issue regarding a stool sample device utilizing cardboard disclosed in Levine (U.S. Patent No. 4,420,353) comprising an absorbent layer surrounded by an outer liquid impermeable sheet layer that prevents contamination of the stool sample was cited by the Examiner. Examiner was found to have ignored the necessary impermeable outer structure that was disclosed in Levine. As with Pagano, the outer layer in Levine was not permeable, since this would preclude the operation of a functioning stool sample device.

An oral hearing is not requested.

Respectfully submitted,

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